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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,435

11/30/2004

Joseph P. Orban III

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3071

7590

06/26/2007

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

06/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,435

Applicant(s)

ORBAN III ET AL.

Examiner

Julian W. Woo

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3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 16-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/22/05, 2/27/07, 4/12/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, drawn to a rigid support structure, classified in class 606, subclass 151.
 - II. Claims 16-22, drawn to a method for reinforcing an anastomotic lumen for a hollow body, classified in class 128, subclass 898.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed can be used in another process, such as cushioning in orthopedic joints.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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3. During a telephone conversation with Francesco Sardone, Reg. No. 47,918, on May 9, 2007, a provisional election was made without traverse to prosecute invention I, claims 1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not certain whether the staples are a structural part of the invention, since the diameter of the inner annular wall is said to be oriented in relation to the staples.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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6. Claims 1, 3, 6-8, 10, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahlke et al. (4,796,603). Dahlke et al. disclose, at least in fig. 3 and in col. 2, lines 50-66; col. 3, lines 29-42, and col. 4, lines 17-43; a rigid support structure including a rigid annular ring (2) having an outer annular wall with a diameter, an inner annular wall spaced a radial distance inward of the outer inner wall and defining a space, a upper wall, a lower wall; the outer and inner annular walls and the upper and inner walls defining a reservoir, and wound closure material (e.g., a polyglactin); where the annular ring has circular cross-sectional profile, where the wound closure material is a hemostat or a sealant that is a synthetic polymer-based material, where the annular outer and inner walls comprise a rigid material that is bioabsorbable (e.g., polyglactin), where the rigid annular ring comprises a plurality of interstitial spaces (between fibers or filaments) configured and adapted to allow staple legs to pass through (if so desired).

7. Claims 1, 6, and 9 are rejected under 35 U.S.C. 102(b) as being rejected by Swartz (5,344,459). Swartz discloses, at least in fig. 1 and in col. 3, line 53 to col. 4, line 30 and col. 5, lines 24-61; a rigid support structure including a rigid annular ring (e.g., 20) having an outer annular wall with a diameter, an inner annular wall spaced a radial distance inward of the outer inner wall and defining a space, a upper wall, a lower wall; the outer and inner annular walls and the upper and inner walls defining a reservoir, and wound closure material (e.g., a gel) that is a gelatin-based hemostat or sealant.

8. Claims 1, 10, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich (6,712,853). Kuslich disclose, at least in fig. 4 and in col. 8, lines 39-52 and col.

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9, line 49 to col. 10, line 17; a rigid support structure including a rigid annular ring (e.g., 12) having an outer annular wall with a diameter, an inner annular wall spaced a radial distance inward of the outer inner wall and defining a space, a upper wall, a lower wall; the outer and inner annular walls and the upper and inner walls defining a reservoir, and wound closure material (e.g., hydroxyapatite), where the annular outer and inner walls comprise a rigid material that is stainless steel or titanium.

9. Claims 1, 14, and 15 are rejected under 35 U.S.C. 102(b) as being rejected by Johnson (5,766,223). Johnson discloses, at least in fig. 1 and in col. 1, line 44 to col. 2, line 20; a rigid support structure including a rigid annular ring (e.g., 2) having an outer annular wall with a diameter, an inner annular wall spaced a radial distance inward of the outer inner wall and defining a space, a upper wall, a lower wall; the outer and inner annular walls and the upper and inner walls defining a reservoir, and wound closure material (12, e.g., ice--which can cause tissue contraction and hemostasis leading to wound closure, where the rigid annular ring includes a plurality of cartridge orientation members (8) or nubs capable of engaging recesses in a surface of a staple cartridge assembly.

10. Note: The introductory statement of intended use ("for use in conjunction with a circular endoscopic stapling instrument having a staple cartridge assembly and an anvil assembly, the staple cartridge assembly having at least one annular arrangement of staple slots and staples positioned in the slots, wherein the support structure maintains a resulting anastomotic lumen in an open condition") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable

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over the devices of Dahlke et al., Swartz, Kuslich, and Johnson, which are capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlke et al. (4,796,603). Dahlke et al. disclose the invention substantially as claimed, but do not disclose the diameters of the outer and inner annular walls as claimed. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to sized the annular walls as claimed, since such modifications would have involved mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

13. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz (5,344,459) in view of Meschan (5,918,384). Swartz discloses the invention

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substantially as claimed. Swartz discloses, in col. 4, lines 5-30, a "cushion"-like support structure that can be modified to a desired level of stiffness. However, Swartz does not disclose a support spoke integrally connected to and extending diametrically across the inner annular wall, where the spoke includes a central hub having a central axial opening capable of receiving a shaft of an anvil assembly. Meschen teaches, at least in fig. 8 and in col. 10, lines 46-55; a cushioning support structure including a support spoke (542) integrally connected to and extending diametrically across an inner annular wall (at 546), where the spoke includes a central hub (546) having a central axial opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Meshan, to include a spoke as claimed in Swartz's device. Such a spoke would increase the stiffness of Swartz's support structure and would allow firmer support of an orthopedic joint, where undue motion of the joint components can be alleviated.

Conclusion


14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cohen (2,514,844), Cenicerros (3,753,266), Werton (5,160,344), and Moore, Jr. et al. (5,782,868) teach annular support structures.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

June 21, 2007